## Maryland Board of Pharmacy Public Board Meeting

## Meeting Minutes July 19, 2017

Name	Title	Present	Absent	Present	Absent
<b>Board Committee</b>		-			
Ashby, D.	Commissioner	X			
Bouyoukas, S.	Commissioner	X			
Evans, K.	Commissioner	X			
Gavgani, M.	Commissioner/President		X		
Hardesty, J.	Commissioner	X			
Leikach, N.	Commissioner	X			
Morgan, K.	Commissioner/Treasurer	X			
Oliver, B.	Commissioner	X			
Peters, R.	Commissioner	X			
St. Cyr, II, Z. W.	Commissioner/Secretary	X			
Toney, R.	Commissioner	X			
Yankellow, E.	Commissioner	X			
<b>Board Counsel</b>					
Bethman, L.	Board Counsel	X			
Felter, B.	Staff Attorney	X			
Board Staf					
Speights-Napata, D.	Executive Director	X			
Fields, E.	Deputy Director of Operations	X			
Evans, T.	Pharmacist Inspector	X			
Brand, E.	Licensing Manager	X			
Logan, B.	Legislation/Regulations Manager	X			
JB					
Janey Patin					
(call center head)					

Subject	Party	Discussion	(Assigned to)	Results
V				
I. Executive Committee Report(s)	A.) M. Gavgani, Board President	Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.		
		1. Z. St. Cyr, II called the meeting to order at 9:35 AM		
		2. Z. St. Cyr, II requested that Board commissioners introduce themselves and also informed guests that the meeting agenda and packet materials were available for review. He advised guests that all packets must be returned at the end of the meeting.		
		3. Z. St. Cyr, II reminded all guests to sign the guest log, indicating whether they would like continuing education credits.		
	B.) Z. St, Cyr, II, Secretary	4. Review and approval of the June 2017 Public Meeting Minutes.	4. Motion to approve by D. Ashby with correction to section B, Item 1c, page 10, which should read, "Motion by Committee to deny," instead of "Motion by Committee to approve." 2 <sup>nd</sup> by K, Morgan.	4. The Board voted to approve this motion.
II. A. Executive Director Report	D. Speights- Napata, Executive Director	1. Operations Updates  a. Personnel Update	a. Investigator Supervisor position has been filled; the new staff member will begin on July 26. The selected candidate for the Lab Scientist	

**Action Due Date** 

Responsible

Subject	Responsible Party	Discussion	Action Due Date (Assigned to)	Results
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		b. Pharmacy Contraceptive Workgroup	Surveyor position will begin in August.  b. Meetings will begin on July 20. The group is set to meet three times before September 1.	
		c. Pharmacist and Pharmacy Technician Rehabilitation Services Provider Solicitation	c. There were no attendees at the pre-bid meeting on the Board's solicitation for a new Rehabilitation Services provider.	
		d. Opioid Prescribing Policy Lisa Burgess, M.D. Chief Medical Officer, Maryland Department of Health e. Naloxone Distribution and Access in Maryland and Maryland's Standing OrderKirsten Forseth, MPHMaryland Department of Health f. USP 800 Overview Thomas Evans Pharmacist Inspector Maryland BOP	d. A presentation was made on opioid use in Maryland and the state's new prescribing guidelines, followed by Q&A from the Board and audience.  e. The presenter provided an overview of the opioid epidemic in Maryland and the harm reduction in this state resulting from the distribution and use of Naloxone.  The USP 800 guidelines describe practice and quality standards for handling hazardous drugs in healthcare settings and help promote patient safety, worker safety, and environmental protection. The overview was followed by Q&A from the Board and audience. Facility compliance with these guidelines is	

Subject	Responsible Party		n	iscussion			Action Due Date (Assigned to)	Results
Subject	1 arty	<u> </u>	<u> </u>	dscussion			(Assigned to)	Results
		2. Meetings	Upda	te			likely to be costly; enforcement by Pharmacy Boards is unclear and a topic of debate. None	
B. Operations Report	E. Fields, Deputy Director/	1. Administ Unit Upd		and Pub	olic Support	(APS)	1. None	
	Operations	2. Managen Unit Upd 3. Budget U	ates		n Systems (N	MIS)	<ol> <li>The six-month contract to develop the mobile inspection tool ends on Friday. The engagement went smoothly and inspectors currently are using the tool in their field inspections.</li> <li>The total revenue for FY 2017 is \$6.3 million with an</li> </ol>	
							expected \$2.4 million fund balance to carry forward in FY 2018.	
C. Licensing	E. Brand, Compliance Manager	<ol> <li>Unit Upda</li> <li>Monthly S</li> </ol>		ics				
		License Type	New	Renewed	Reinstated	Total		
			33	176	0	1,280		
		Pharmacy	22	0	1	2,112		
		Pharmacist	80	410	0	11,388		

Subject	Responsible Party		Γ	Discussion			Action Due Date (Assigned to)	Results
		•						
		Vaccination	18	0	0	4,433	TI .	
		Vaccination	10	U	U	4,433		
			•					
		Pharmacy	9	0	0	50		
		Intern -						
		Graduates						
		Pharmacy	68	18	0	976		
		Intern -						
		Students						
		Pharmacy	119	256	7	9,817		
		Technician						
		TOTAL	349	860	8	30,056		
D. Compliance	T. Evans,	1. Unit Upd	lates	I				
-	Pharmacist Inspector	2. Monthly	Statis	tics				
	Inspector	Complaints & In	ivestig	gations:				
		New Complaints Resolved (Includi Actions within Go Final disciplinary Summary Actions Average days to o	ing Ca oal – 4 actior s Take	4/55 ns taken – n – 2				
		Inspections:						
		Annual Inspection						
		Opening Inspection						
		Closing Inspection Change Inspection						
		Special Investigat		3				
E. Legislation &	B. Logan,	1. COMAR 10.34			f of Profic	ciency in	1. Bill signed and was posted on June	
Regulations	Legislation and	English					23 <sup>rd</sup> , with effective date of July 3 <sup>rd</sup> .	

Subject	Responsible Party	Discussion	Action Due Date (Assigned to)	Results
2 5 <b>,</b>			(	2333333
	Regulations Manager	2. COMAR 10.34.37 Pharmacy Permit Holder Requirements — Wholesale Distribution and Non- Resident Pharmacy Operations	2. Posted for comments on July 7 <sup>th</sup> in the MD Registry. The Open comment period ends August 7 <sup>th</sup> . If no comments are received, the Board may be able to adopt the regulation at its August meeting.	
		3. COMAR 10.34.05.05 Security Responsibility.  4. COMAR 10.34.34.05 Pharmacy Students.  5. COMAR 10.34.40 Pharmacist Administration of	<ul> <li>3. Regulations to be completed by July 30<sup>th</sup>.</li> <li>4. A notice of proposed action was submitted based upon non-substantive, formatting comments; recommended changes to Section D; a new section will be added and resubmitted.</li> <li>5. The first stakeholders workgroup meeting will be held on July 20<sup>th</sup>. The final regulation is due on September 1, 2018.</li> </ul>	
		Self-Administered Drugs		
III. Committee Reports A. Practice Committee	R. Peters, Chair	1. Contraceptives in Vending Machines  2. Jeff Kunkel	1. The committee re-reviewed this request based upon the presentations and discussion at the BOP's June public meeting. Continuing concerns were raised with regard to access to the medication and the absence of counseling. The committee noted that the BOP has no regulatory authority in this area and recommends the Board make no recommendation to the Deputy Secretary, 2 <sup>nd</sup> by J. Hardesty.	1. The Board voted to approve this action.

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		In order to be part of the solution to the opioid epidemic, our hospital and our outpatient pharmacy are looking to take proactive steps to help place Narcan (the agent used to reverse the effects of opioids) into the hands of patients and caregivers in need in response to the new standing order placed on 06/01/17 by Dr. Howard Haft. I would like to explain a process and determine if this is within the scope of MD Pharmacy Law.	2. Motion to approve response as prepared, 2 <sup>nd</sup> by R. Toney.	2. The Board voted to approve this motion.
		Our outpatient pharmacy would like to package Narcan Kits (containing Narcan, 2 CPR shields, and rubber gloves) and label the product with a label with all necessary label requirements except patient name, RX #, expiration date, and date filled. Our pharmacy would place this product into our emergency room automated dispensing device (PYXIS) as we are an Ambulatory Care pharmacy within an acute care hospital. When a patient presented to the emergency room (after our pharmacy has closed) the emergency room would dispense the Narcan Kit and complete the balance of the label (patient name, RX #, expiration date, and date dispensed.)		
		Upon dispensing (by next day), our Emergency department will provide us a log with (patient name, RX #, expiration date, and date dispensed) and our pharmacy will then enter the "RX" into our pharmacy dispensing system for record keeping purposes and affix the RX#, date, expiration date, and specific patient to the RX.  The notables here are we will have a pharmacist either		
		on site in the hospital or on call and available via phone 24/7 when both our inpatient pharmacy and outpatient pharmacy are closed. So it would be		

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Subject	Party	Discussion	(Assigned to)	Results
		feasible to have the product dispensed when no		
		pharmacist was present in the building.		
		<b>Response:</b> The Board reviewed your proposal		
		regarding alternative options to dispensing Narcan		
		when the hospital pharmacy is closed. If the hospital		
		wishes to utilize an automated medication system to		
		dispense naloxone under the auspices of the hospital		
		pharmacy permit, the system must comply with the		
		Board's automation regulations, COMAR 10.34.28.05.		
		The regulations require, among other things, that a		
		pharmacist reviews each order for medication: (1) after		
		the order has been entered into the system; and (2)		
		before the system permits access to the medication. Alternatively, the attending physician in the emergency		
		room may dispense the Naloxone if the physician has a		
		dispensing permit from the Board of Physicians. The		
		Board recommends that you present this issue to the		
		appropriate committee within your facility to determine		
		the mechanism that will best suit the needs of your		
		patients		
B. Licensing	D. Ashby,	1. Review of Pharmacist Applications:	1a. Motion by committee to approve,	
Committee	Chair	a) I. Lio- Email request of NAPLEX score	2 <sup>nd</sup> by N. Leikach.	1 TPI D 1 . 1.
		transfer extension. She graduated in 2016 and score transferred to MD. She applied		1a. The Board voted to
		to MD as an exam applicant with her		approve this motion.
		NAPLEX score only valid for one year,		
		until June 3, 2017. She is requesting that		
		the Board grant her a NAPLEX score		
		transfer extension for up to four months,		
		until October 3, 2017, to ensure that her		
		application and scores will still be valid		
		when she takes the MPJE exam a second		
		time.		

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		Licensing Committee's Recommendation: Approve  b) J. Diala- Request for application expiration date extension. She passed the NAPLEX on March 8, 2017, and had the score transferred to MD. Due to lack of availability, the earliest date she was able to schedule for the MPJE was June 19, 2017. The application expired on June 14, 2017. She is unemployed and, at this time, it would be very difficult for her to pay the application fee again.  Licensing Committee's Recommendation: Deny	1b. Motion by committee to deny, 2 <sup>nd</sup> by S. Bouyoukas.	1b. The Board voted to approve this motion.
		<ol> <li>Review of Pharmacy Intern Applications: NONE</li> <li>Review of Pharmacy Technician Applications: NONE</li> <li>Review of Distributor Applications: NONE</li> <li>Review of Pharmacy Applications:</li> <li>Applicant #113198- In 2011, the Florida Department of Health filed a complaint against the pharmacy for purchasing from a Distributor not licensed in Florida. Pharmacy was placed on probation and paid prosecution costs of \$1,874.74. Owner disagrees with the Board's policy that the MD licensed pharmacist must be on site at the pharmacy.</li> </ol>	5a. Following discussion, a substitute motion by D. Ashby that the Maryland licensed pharmacist should be regularly available, on site, as needed to meet Maryland patients' needs, 2 <sup>nd</sup> by B. Oliver.	5a. The Board voted to approve this motion.

	Responsible		Action Due Date	
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		<ul> <li>Licensing Committee's Recommendation:         <ul> <li>Board states that pharmacist has to be readily available at the pharmacy for at least a portion of the time.</li> </ul> </li> <li>Review of Pharmacy Technicians Training Programs:         <ul> <li>Brightwood College- Requesting approval as a training program.                 <ul></ul></li></ul></li></ul>	6a. Motion by committee to approve.  2 <sup>nd</sup> by E. Yankellow.  7a. following discussion, a substitute motion to table discussion for further committee review and language drafting was made by R. Toney, 2 <sup>nd</sup> by J. Hardesty.	<ul><li>6a. The Board voted to approve this motion.</li><li>7a. The Board voted to approve this motion.</li></ul>
C. Public Relations Committee	E. Yankellow, Chair	Annual CE Breakfast will be held on October 22 <sup>nd</sup> this year. The presenters and agenda have been confirmed and the Board approved at its June meeting a one-time honorarium for one of the presenters. The presentations will be available by webinar. Board staff will have additional training for the webinar production.  The deadline for Newsletter article submission is August 19 <sup>th</sup> , for articles to be printed in the Newsletter that will be released at the end of the summer.		
D. Disciplinary	K. Morgan, Chair	Disciplinary Committee Update None at this time.		

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E. Emergency	N. Leikach,	<b>Emergency Preparedness Update:</b>		
Preparedness	Chair			
Task Force		The next meeting will be held on September 13 <sup>th</sup> .		
IV. Other	M. Gavgani,			
Business & FYI	President			
V. Adjournment	M. Gavgani, President	Z.St. Cyr, II, asked for a motion to close the Public Meeting and open a Closed Public Session at 12:10 PM.	Motion to close Public Board Meeting by D. Ashby, 2 <sup>nd</sup> by K. Evans.	The Board voted to approve this motion.
		Z. St. Cyr, II, convened a Closed Public Session for the purpose of engaging in medical review committee deliberations regarding confidential information in applications in accordance with the Open Meetings Act, General Provisions Article, Section3-305 (b) (7) and (13).		
		The Closed Public Session was adjourned and immediately thereafter, Z. St. Cyr, II, convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members		
		present at the Public Meeting continued to participate in the Administrative Session.		